

SEALED

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Danville Division

CLERK'S OFFICE U.S. DIST. COURT
AT ROANOKE, VA
FILED
For Diller
MAY 17 2013

JULIA C. DUDLEY, CLERK
BY: *J. Craft*
DEPUTY CLERK

THE UNITED STATES OF AMERICA,)

ex rel.)

JOSEPH M. THOMAS)

2005 Summerhouse Road)

Cary, North Carolina)

BRINGING THIS ACTION ON)

BEHALF OF THE UNITED STATES)

OF AMERICA)

c/o Timothy J. Heaphy, Esq.)

United States Attorney)

Western District of Virginia)

310 First Street, SW, Room 906)

Roanoke, VA 24011)

and)

c/o Eric H. Holder, Jr., Esq.)

Attorney General of the United States)

Department of Justice)

10th & Constitution Avenue, N. W.)

Washington, D. C. 20530)

Plaintiff,)

v.)

DUKE UNIVERSITY,)

Serve:)

Pamela Bernard, Registered Agent)

310 Blackwell Street, 4th Floor)

Durham, NC 27710)

DUKE UNIVERSITY HEALTH)

SYSTEM, INC.)

Serve:)

Pamela Bernard, Registered Agent)

310 Blackwell Street, 4th Floor)

Durham, NC 27710)

DR. WILLIAM M. FOSTER, Ph.D)

CIVIL ACTION NO. *4:13-cv-00017*

FILED UNDER SEAL PURSUANT TO
31 U.S.C. § 3730(b)(2)

COMPLAINT FOR VIOLATIONS
OF FEDERAL FALSE CLAIMS ACT
(31 U.S.C. §§3729 - 3733)

JURY TRIAL DEMAND

ERIN N. POTTS-KANT

Defendants.

COMPLAINT

Joseph M. Thomas brings this action on behalf of the United States of America against the Defendants, Duke University, Duke University Health Systems, Inc., Dr. William M. Foster, Ph.D., and Potts-Kant, pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, and alleges as follows:

INTRODUCTION

1. Duke University is one of the premier research institutions in the United States. It annually spends almost \$1 billion per year on research, and over half of those research dollars come from the federal government. Research conducted at Duke carries with it a level of esteem and credibility. Both the public and the scientific community expect integrity from Duke's research, and the federal government expects — in fact, requires — honesty in the use of the public's tax dollars.

2. Falsifying and manipulating medical scientific research has obvious and wide ranging public health implications. When federal tax money is used to conduct fraudulent research and when falsified research is used to procure more federal dollars, those actions affect the public. Duke agrees. Duke's Policy Governing Misconduct in Research states: "Duke University strives to foster an atmosphere of honesty and trust in which pursuit of knowledge can occur. Integrity of research forms the foundation of respect among scholars and students and between the academic world and the public." Duke University has an Office of Research Support tasked with addressing misconduct in research.

3. Erin Potts-Kant was the Clinical Research Coordinator within the Pulmonary Division of Duke University Medical Center, and her job duties specifically called upon her to “ensure compliance with protocol guidelines and requirements of regulatory agencies ... and to identify problems and/or inconsistencies.”

4. Instead, Ms. Potts-Kant engaged in systematic and near-universal research fraud. This research fraud ranged from manipulating data to outright manufacture of data in lieu of actually performing experiments. Using this fraudulent research, Erin Potts-Kant co-authored 38 publications in scholarly journals with fellow Duke University researchers.

5. The impact of the research manipulation was not limited to the 38 publications co-authored by Potts-Kant. These tainted publications have been cited in 417 scholarly articles.

6. Duke University, through its agents and employees, used these fraudulent research results and data in grant applications and interim progress reports to the Public Health Service, National Institutes of Health (NIH), and other Federal agencies responsible for administering scientific research grants.

7. Duke University also falsely certified compliance with the applicable regulations governing research integrity, including 42 C.F.R. Parts 50 and 93 and the NIH Grants Policy Statement.

8. In all, the fraudulent research formed the basis for over \$112 million in grant funding to Duke University.

9. Since this research fraud became known within the Pulmonary Division, Duke University and its Office of Research Support have, upon information and belief, concealed this fraud from the Federal agencies responsible for its grant funding.

10. Relator Joseph Thomas (hereinafter “Thomas” or “Relator Thomas”) discovered

Defendants' wrongful conduct while he was a Laboratory Research Analyst employed by Duke University Health Systems, Inc. He conducted his own investigation in furtherance of this False Claims Act *qui tam* action and disclosed his findings to the United States Government prior to filing this action.

11. Relator Thomas, on behalf of himself and the United States, seeks to redress this significant wrong. Relator Thomas has direct and independent knowledge that Defendants violated the False Claims Act by, among other things, submitting grant proposals and subsequent interim reports premised upon fraudulent research data.

JURISDICTION AND VENUE

12. Relator brings this action on behalf of himself and on behalf of the United States for violations of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* This Court has federal subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and 31 U.S.C. §§ 3732 and 3730(b).

13. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because Defendant Duke University Health Systems, Inc., can be found in and transacts business in this District.

14. Venue is proper in this judicial district under 31 U.S.C. § 3732(a) because, at all times material and relevant hereto, Defendant Duke University Health Systems, Inc., transacted business in the Western District of Virginia at its Cardiovascular Surgery of Danville clinic in Danville, Virginia; and Defendant Duke University transacts business in the Western District of Virginia.

15. Relator Thomas' claims and this Complaint are not based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party, as enumerated in 31 U.S.C. § 3730(e)(3).

16. To the extent that there has been a public disclosure unknown to the Relator, he is the “original source” and meets the requirements pursuant to 31 U.S.C. § 3730(e)(4)(B).

PARTIES

17. Relator Thomas is a citizen of the United States and a resident of North Carolina. At all times relevant herein, Relator Thomas was an employee of Duke University Health Systems, Inc. Relator Thomas is a Laboratory Research Analyst II. In this capacity, he develops, designs and conducts experiments for the Pulmonary, Asthma and Critical Care Division (“Pulmonary Division”). By virtue of his position and background, Relator Thomas became aware of research fraud within the Pulmonary Division at Duke University Medical Center and gained direct and independent knowledge of the allegations contained in this Complaint.

18. Relator Thomas is the original source of the information provided herein to the United States. He has direct and independent knowledge of the information upon which the allegations are based and has voluntarily provided this information to the Government, prior to the filing of this action under seal, as required by 31 U.S.C. § 3730(b)(2), before publicly proceeding with this action pursuant to the False Claims Act.

19. Defendant Duke University is a private university located in Durham, North Carolina, which, among other things, performs scientific research. Duke University also operates a Office of Research Support to provide oversight of the scientific research performed at Duke and to ensure that research complies with NIH and other federal policies. Duke University transacts business in the western district of Virginia.

20. Defendant Duke University Health System, Inc., is a health care services company located in Durham, North Carolina. Duke University Health System, Inc., is a subsidiary of Duke University, and it runs Duke University Medical Center. It also operates in

and transacts business in this District by offering medical services in Danville, Virginia.

21. Defendant Erin Potts-Kant (hereinafter “Potts-Kant”) is an individual who was the Clinical Research Coordinator II in the Division of Pulmonary and Critical Care Medicine at Duke University Medical Center.

22. Defendant Dr. William M. Foster, Ph.D. (hereinafter “Dr. Foster”), is a Research Professor of Medicine in the Division of Pulmonary and Critical Care Medicine at Duke University Medical Center. Dr. Foster was Potts-Kant’s direct supervisor.

FACTUAL ALLEGATIONS

BACKGROUND OF RELATOR

23. Relator Thomas began his work at Duke University in 2008. Initially, he worked within the laboratory of Dr. Jo Rae Wright, Dean of the Duke University Graduate School (hereinafter “Dr. Wright”). This laboratory was within the Cell Biology Department of Duke University Medical Center. In his capacity as a Research Tech II (and later Laboratory Research Analyst), he performed experiments, analyzed data and co-authored scholarly publications.

24. In December 2011, Dr. Wright died after a long battle with cancer and her laboratory staff was split up and moved to different laboratories. Relator Thomas remained in the same laboratory for two months before moving to the laboratory of Dr. Monica Kraft (hereinafter “Dr. Kraft”) in the Pulmonary Division. He has worked within Dr. Kraft’s laboratory from February 2012 to the present time.

25. The Pulmonary Division is made up of several researchers who possess either a Ph.D. or Medical Doctor (“M.D.”) degree. These researchers are designated as Principal Investigators (“PIs”) because they direct and manage research and are designated as recipients of grant funding. Several of the relevant PIs in the Pulmonary Division are Dr. Kraft, Dr. John

Hollingsworth (“Dr. Hollingsworth”), Dr. Loretta Que (“Dr. Que”), and Dr. Foster. The Pulmonary Division also conducts research with other physicians and scientists outside the division.

26. Each PI has a laboratory that operates under their supervision. Relator Thomas is a Laboratory Research Analyst II for Dr. Kraft. Potts-Kant was a Clinical Research Coordinator who worked for Dr. Foster. Dr. Julie Ledford (“Dr. Ledford”) is an Assistant Research Professor who works for Dr. Hollingsworth.

RESEARCH FRAUD OF POTTS-KANT

27. Potts-Kant was hired by Duke University in 2006 and began work with Dr. Foster within the Pulmonary Division.

28. Dr. Foster’s Airway Physiology Laboratory operated in many respects as a “core laboratory,” meaning that many other laboratories would submit experiments to Dr. Foster’s laboratory to conduct on their behalf. Rather than accepting payment or reimbursement for conducting these experiments, as is typically done in other divisions and other institutions, Dr. Foster’s laboratory would instead request that they be cited as co-authors on the publications stemming from their work and be listed on grants.

29. The Airway Physiology Laboratory focused primarily on studying the effects of pathogens, chemicals, medications and environmental factors on the airways of laboratory mice. Potts-Kant’s work with Dr. Foster’s laboratory involved operating several machines that measured and assessed pulmonary physiology. These machines included the flexiVent and a Bio-Plex, along with performing routine laboratory assays.

30. The flexiVent machine, manufactured by Scireq, measures airway responsiveness. It does this by force-ventilating a mouse and measuring the amount of resistance to air as are is

ventilated into the mouse pulmonary system. It measures other physiological characteristics as well.

31. The Bio-Plex machine, or Luminex, analyzes biological material samples and identifies proteins within the sample. It can also quantify the amount of certain proteins in biological samples.

32. Potts-Kant's position was that of Clinical Research Coordinator II. Duke University's Job Description (**Exhibit A**) for this position calls for the Clinical Research Coordinator II to "coordinate and participate in a variety of complex activities involved in the collection, compilation, documentation and analysis of clinical research data."

33. The job description requires a Clinical Research Coordinator II to "[e]nsure compliance with protocol guidelines and requirements of regulatory agencies; identify problems and/or inconsistencies.."

34. The job description requires a Clinical Research Coordinator II to "[e]valuate and interpret collected clinical data in conjunction with principal investigator(s) as appropriate; prepare oral presentations or written reports and analyses setting forth progress, trends and appropriate recommendations or conclusions."

35. The job description requires Clinical Research Coordinator II to supervise and train more junior personnel; another task of the position is listed as "[p]rovide guidance to lower level personnel involved in planning, implementation and evaluation of clinical studies. Assist in training new personnel."

36. Dr. Foster coordinated the purchase of the flexiVent machine for his laboratory around the time of Potts-Kant's hire. Prior to the purchase of the flexiVent machine, these types of physiological measurements were obtained through the APTI machine operated by Dr. David

Schwartz, the Chief of Pulmonary Division prior to Dr. Paul Noble.

37. When Potts-Kant began operating the flexiVent machine, she obtained results that were inconsistent with the previous APTI machine.

38. Despite these inconsistent findings, Dr. Foster and the staff of the Pulmonary Division generally dismissed the discrepancy in findings.

39. Throughout her entire employment with Duke University in the Pulmonary Division, Potts-Kant committed research fraud and misconduct on nearly every experiment or project with which she was involved. This fraud took many forms. On some experiments, she would conduct the experiment and later alter the data to be more statistically significant. She accomplished this fraud by removing values from the raw data that fell outside the standard deviation, or changing values to be more consistent with other experimental values, thereby making the experiments' results more statistically significant.

40. Potts-Kant' fraud was sometimes more direct and brazen. She sometimes did not run the experiments at all, instead manufacturing data that would correspond to the hoped-for outcome of the experiment.

41. Potts-Kant committed this fraud in a several different ways. Sometimes she would download the raw data from an experiment from the machine in a text format before converting the data into an Microsoft Excel spreadsheet. Once in Excel format, Potts-Kant would review the data and make changes to the data that accomplished her objective before forwarding the manipulated files to the investigators.

42. On other occasions, Potts-Kant would deliberately fail to expose the mice to the chemical, medication or environmental condition as called for by the experiment.

RESEARCH FRAUD FORMED BASIS FOR SCHOLARLY PUBLICATIONS

43. Potts-Kant, collaborating with a variety of Duke University faculty and researchers, used the results of her fraudulent experiments to co-author 38 scientific papers and journal articles. The articles that, upon information and belief, are affected by her research fraud are attached in **Exhibit B**, which is incorporated by reference.

44. Dr. Ledford informed Relator Thomas that no raw data exists at all for some experiments supposedly conducted by Potts-Kant, indicating that these experiments did not take place.

45. Relator Thomas has seen the discrepancies between actual and raw data; they demonstrate manipulation and falsification of research by Potts-Kant.

46. Relator Thomas has discussed this research fraud with Dr. Ledford, Dr. Que, Charles Giamberardino and other Pulmonary Division personnel. These research personnel have explained to Relator Thomas that upon review of Potts-Kant's research, all such research is either non-existent, falsified, manipulated or fraudulent in some manner. Based upon their statements to him, Relator Thomas understands that all work completed by Potts-Kant is manipulated or fraudulent in some way. A more detailed description of the fraudulent data follows below.

SUMMARY OF NIH GRANT APPLICATION PROCESS

47. The National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services, is the primary federal agency supporting medical research in the United States. Through a competitive application process, the NIH awards grants to research institutions across the country and world.

48. As a federal grantor agency, the NIH is "responsible to Congress and the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but does so

cost-effectively and in compliance with applicable rules and regulations.” (NIH Grants Policy Statement, I § 2, “The National Institutes of Health as a Grant-Making Organization: Roles and Responsibilities,” p. I-27).

49. The NIH seeks to “ensure integrity and accountability in its grant award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for grantee organizations.” (NIH Grants Policy Statement, I § 2, “The National Institutes of Health as a Grant-Making Organization: Roles and Responsibilities,” p. I-27) (emphasis added).

50. Most applications for NIH grants are submitted electronically. The Electronic Research Administration (“eRA Commons”) is the platform for transactions related to the receipt, review, and administration of NIH grant applications. Applicants register with the eRA Commons database through their home institution’s grants administration office.

51. When electronically submitting its application, a research organization makes numerous certifications to the NIH regarding its request for and proposed use of federal funds. An organization certifies that it has “the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application.” (NIH Grants Policy Statement, I § 2.3.6, “Legal Implications of Applications,” p. I-35).

52. Upon submission of its application, a research organization further certifies compliance with public policies governing objectivity in research, research integrity, and research misconduct. A research organization certifies that it has in place administrative procedures for reviewing, investigating, and reporting allegations of research misconduct in

science conducted at, or sponsored by, the organization. (NIH Grants Policy Statement, II § 4.1.26, “Research Misconduct,” p. IIA-37).

53. In addition, a research organization certifies that no federal funding will be used to disseminate information that is deliberately false or misleading. (NIH Grants Policy Statement, II § 4.2.3, “Dissemination of False or Deliberately Misleading Information, p. IIA-41).

54. Applications for NIH grants are subject to peer review by a panel of experts in appropriate scientific areas and, if successful, advance to a pre-award processing stage for additional evaluation. (NIH Grants Policy Statement, I §§ 2.4, “The Peer Review Process,” 2.5, “Completing the Pre-Award Process, p. I-50 – I-61).

55. Applicants approved for funding receive a Notice of Award, a legally binding document signed by an NIH Grants Management Officer that contains or references all the terms and conditions of the grant. Accordingly, acceptance of an award from the NIH obligates the grantee to be aware of and comply with the terms and conditions of award. (NIH Grants Policy Statement, II § 3, “Terms and Conditions of NIH Grant Awards,” p. IIA-1).

56. The NIH requires that grantees periodically submit financial and progress reports. Progress reports inform the NIH of the grantee’s accomplishments, including publications and inventions resulting from the award; personnel and location changes; budget updates; and other information pertaining to the grantee’s use of funds. (NIH Grants Policy Statement, II § 8.4.1, “Reporting,” p. IIA-105 – IIA-110).

57. For multi-year funded (MYF) awards, progress reports serve as the basis for the NIH’s continued support of the project. MYF awards are when the project period and budget period are the same and are longer than one year, and the award is funded from a single

appropriation. Progress reports for MYF awards are due annually on or before the anniversary of the budget/project start date of the award. (NIH Grants Policy Statement, II § 8.4.1.3, “Progress Reports for Multiyear Funded Awards,” IIA-109 – 110).

58. In submitting a progress report, the grantee organization certifies compliance with the terms and conditions of the Notice of Award and verifies the accuracy and validity of all administrative, fiscal, and scientific information in the progress report. The grantee organization further certifies its accountability for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the progress report. (NIH Grants Policy Statement, II § 8.4.1, “Reporting,” p. IIA-105 – IIA-110).

59. In their financial reports, grantees must submit cash transaction data (quarterly) and expenditures (annually). As with progress reports, the grantee organization certifies compliance with the terms and conditions of the Notice of Award and verifies the accuracy and validity of all information contained in the report. (NIH Grants Policy Statement, II § 8.4.1.5, “Financial Reports,” p. IIA-110 – IIA-111).

60. At the conclusion of a funded project, the grantee is also required to submit certain closeout documents to the NIH, including a final progress report, final invention statements and certifications, and a final financial status report. Again, the grantee organization certifies compliance with the terms and conditions of the Notice of Award and verifies the accuracy and validity of all information contained in the final reports. (NIH Grants Policy Statement, II § 8.6, “Closeout,” p. IIA-119 – IIA-121).

61. At closeout, final progress reports summarize the grantee’s accomplishments, significant results (positive or negative), and list publications resulting from the grant. Again, the grantee organization certifies compliance with the terms and conditions of the Notice of Award

and verifies the accuracy and validity of all information contained in the final reports. (NIH Grants Policy Statement, II § 8.6.2, “Final Progress Report,” p. IIA-120).

62. The NIH policy statement also provides for civil and criminal enforcement of fraud, waste, and abuse of NIH grant funds. According to NIH policy, examples of fraud, waste, and abuse include, but are not limited to:

embezzlement, misuse, or misappropriation of grant funds or property, and false statements, whether by organizations or individuals. Other examples include theft of grant funds for personal use; using funds for non-grant-related purposes; theft of federally owned property or property acquired or leased under a grant; charging the Federal government for the services of “ghost” individuals; charging inflated building rental fees for a building owned by the grantee; submitting false financial reports; and submitting false financial data in bids submitted to the grantee (for eventual payment under the grant).

(NIH Grants Policy Statement, I § 2.3.10, “Fraud, Waste and Abuse of NIH Grant Funds,” p. I-45).

FRAUDULENT PUBLICATIONS FORMED BASIS FOR PUBLIC HEALTH SERVICE AND OTHER FEDERAL GRANTS

63. Duke University applied for and received 53 grants over multiple years totalling approximately \$112 million that were directly premised upon and affected by the research fraud of Potts-Kant. The grants cited as supporting Potts-Kant’s work are listed in **Exhibit C**.

64. Publications and grants mutually cite one another. While publications report which grants financially supported their research, grant holders provide the names of publications to grant agencies in order to demonstrate to the grant agency the work product resulting from the grant money. The grant agencies rely upon this information in making decisions to award grants over multiple years.

65. For both grants and during all relevant times, Duke University cited the fraudulent research described below and the resulting scientific articles in its Interim Progress Reports and

Close Out Reports.

Publication Containing Falsified Data - *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A) -/- mice*

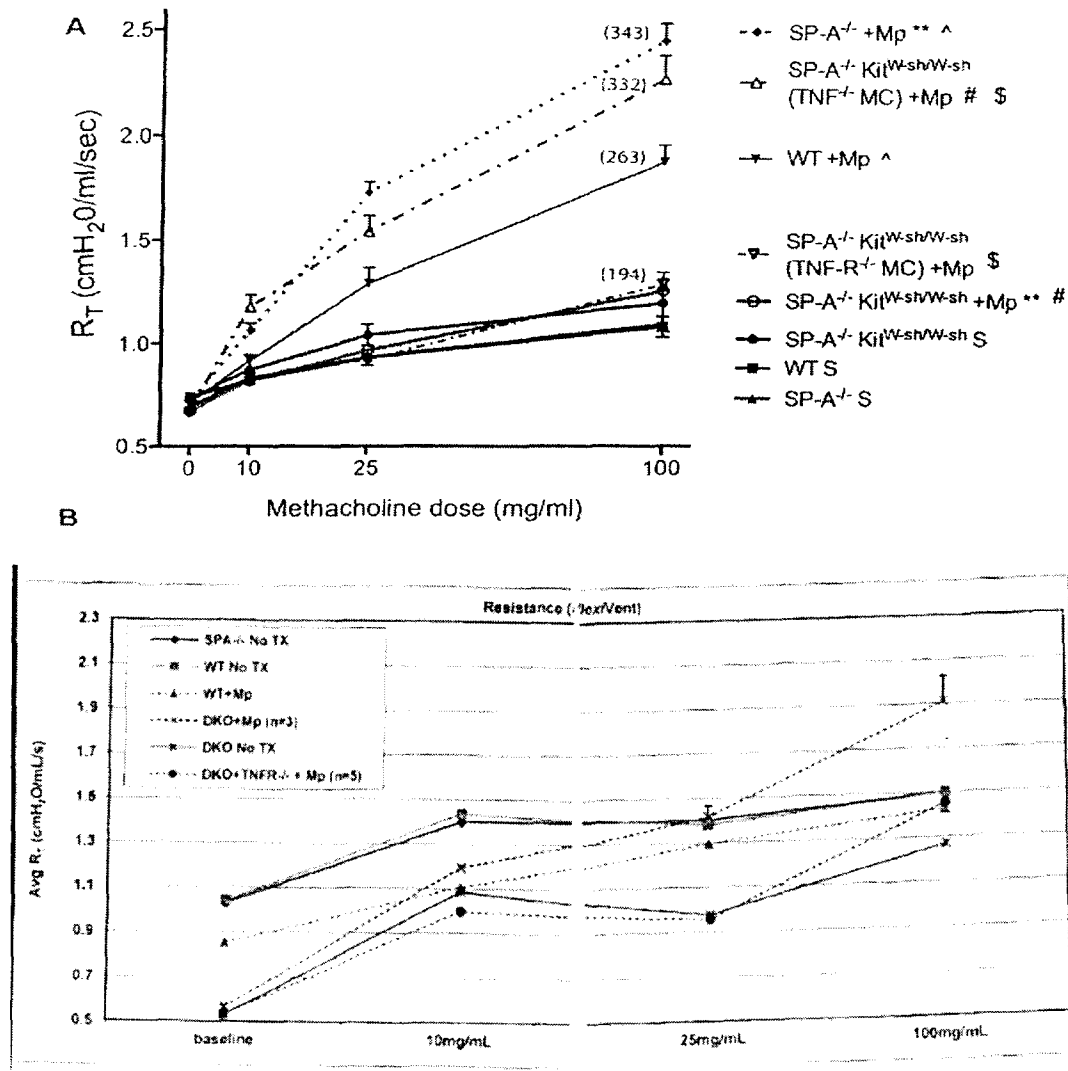
66. Relator Thomas provides several examples of Potts-Kant's fraud in **Exhibit D**. These documents are copies of spreadsheets made by Dr. Ledford on which she made notations indicating that the research had been manipulated. Dr. Ledford made these spreadsheets in the course of uncovering Potts-Kant's fraud and showed these documents to Relator Thomas. These series of experiments were conducted to determine the role of tumor-necrosis factor produced by mass cells, a protein involved in lung inflammation. flexiVent data in this context is important because it provides an in-vivo context of airway physiology that is very compelling.

67. **Exhibit D**, at 1-3, contains a comparison of raw data with manipulated data compiled by Dr. Ledford. The column "Actual Numbers" on each page contains data from the flexiVent machine. Dr. Ledford was comparing these values with those in the "R" column. "R" stands for Resistance, which is an important standard of measurement in the context of this experiment. As Dr. Ledford notes on the margins of her page, these values have been "Manipulated."

68. Relator Thomas, reviewing the fraudulent data discussed in **Exhibit D**, identifies this data as forming the basis for the scientific article *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A) -/- mice*. Bethany J. Hsia, Ph.D., Julie Ledford, Ph.D., Potts-Kant-Kant, B.S., Vinayak S. Nikam, B.S., Njira L. Lugogo, M.D., W. Michael Foster, Ph.D., Monica Kraft, M.D., Soman N. Abraham, Ph.D., and Jo Rae Wright, Ph.D., *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A) -/- mice*. (**Ex. B, at Relator_000202.**)

69. **Exhibit D**, at 4, contains a graph representing airway resistance at varying levels

of methacholine administration (Second graph below). This graph is the true raw data from the experiment. Upon information and belief, Figure 6A the above-referenced article represents the same graph with manipulated data (First graph below).



70. This scientific article, premised upon fraudulent research, cites financial support of National Institutes of Health grants F32-HL091642 and PO1-AI81672.

71. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of

compliance made by applicants to NIH.

Publication Containing Falsified Data - *Airway Smooth Muscle Relaxation is Impaired in Mice Lacking the p47 Subunit of NAD(P)H Oxidase*

72. In 2007, Potts-Kant performed experiments that contributed to the paper entitled *Airway Smooth Muscle Relaxation is Impaired in Mice Lacking the p47 Subunit of NAD(P)H Oxidase*. (Ex. B, at Relator_000029.)

73. Upon information and belief, Potts-Kant falsified data that went into this scientific paper, specifically the data contained in Figures 8 and 9 of this paper.

74. This paper was published in January 2008.

75. Prior to publication, a portion of the work contained in this paper was presented to the American Thoracic Society.

76. Upon information and belief, in 2007, Dr. Wayne Mitzner, Director of the Respiratory Biology/Lung Disease Program at Johns Hopkins University, questioned the validity of the data generated by Potts-Kant and Dr. Foster. Due to the low statistical error of the data despite the low sample sizes, Dr. Mitzner believed the data to be manipulated or doctored. Upon information and belief, without checking the raw data, Dr. Foster vigorously defended Potts-Kant and his laboratory.

77. Dr. Jamie Cyphert, a researcher with the NIEHS, also raised questions about the validity of the data produced by the Foster Airway Physiology Laboratory.

78. Dr. Cyphert attempted to reproduce the experiments of Potts-Kant and Dr. Foster but was unable to do so.

79. Dr. Cyphert requested that Potts-Kant and Dr. Foster share with her their computer scripts for the flexiVent machine so that she might reproduce their work. They refused.

80. Dr. Foster refused to share the computer script for the flexiVent machine with anyone.

Publication Containing Falsified Data - *Maternal Diesel Inhalation Increases Airway Hyperreactivity in Ozone-Exposed Offspring*

81. Potts-Kant co-authored a scientific paper entitled *Maternal Diesel Inhalation Increases Airway Hyperreactivity in Ozone-Exposed Offspring*. (Ex. B, at Relator_000226.)

82. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent and Luminex machines. The data supposedly produced by these experiments are contained within Figures 1, 3 and 4 of the article.

83. Upon information and belief, Potts-Kant did not actually perform the experiments at all, but rather falsified the data contained within the paper.

84. This scientific paper was published in original form on July 23, 2011 by the American Journal of Respiratory Cell and Molecular Biology.

85. This scientific article, premised upon fraudulent research, cites financial support of Environmental Protection Agency Children's Environmental Health Center award RD 83329301 and NIH grant ES-016347.

86. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Protective Role of T-bet and Th1 Cytokines in Pulmonary Grant-verses-Host Disease and Peribronchiolar Fibrosis*

87. Potts-Kant co-authored a scientific paper entitled *Protective Role of T-bet and Th1 Cytokines in Pulmonary Grant-verses-Host Disease and Peribronchiolar Fibrosis*. (Ex. B,

at Relator_000429.)

88. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figure 2 of the article.

89. Upon information and belief, Potts-Kant falsified the data contained within the paper.

90. This scientific paper was published in original form on April 17, 2011 in the American Journal of Respiratory Cell and Molecular Biology.

91. This scientific paper, premised upon fraudulent scientific research, cites financial support from International Society for Heart and Lung Transplantation Research Award 6860201585 and NIH Grants 1P50-HL084917, 1F32HL090265-01, RR024 127-03, 1P30 ES-011961-01A1, 1 K24 HL91140-01A2 and A1081672.

92. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Ozone Inhalation Promotes CX3CR1-dependent Maturation of Resident Lung Macrophages which Limit Oxidative Stress and Inflammation*

93. Potts-Kant co-authored a scientific paper entitled *Ozone Inhalation Promotes CX3CR1-dependent Maturation of Resident Lung Macrophages which Limit Oxidative Stress and Inflammation*. (Ex. B, at Relator_000285.)

94. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figure 5 of the article.

95. Upon information and belief, Potts-Kant did not actually perform the experiments at all, but rather falsified the data contained within the paper.

96. This scientific paper was published in final form on November 1, 2011 in The Journal of Immunology.

97. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126, ES016347 and HL077291.

98. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Extracellular Matrix Protein Mindin is Required for the Complete Allergic Response to Fungal-Associated Proteinase*

99. Potts-Kant co-authored a paper entitled *Extracellular Matrix Protein Mindin is Required for the Complete Allergic Response to Fungal-Associated Proteinase*. (**Ex. B, at Relator_000120.**)

100. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent and Luminex machines. The data supposedly produced by these experiments are contained within Figures 1 and 3 of the article.

101. Upon information and belief, Potts-Kant falsified the data contained within the paper.

102. This scientific paper was published in final form on September 20, 2011 in Journal of Allergy and Therapy.

103. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126, ES020426 and HL77291.

104. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *S-nitrosoglutathione supplementation to ovalbumin-sensitized and – challenged mice ameliorates methacholine-induced bronchoconstriction*

105. Potts-Kant co-authored a paper entitled *S-nitrosoglutathione supplementation to ovalbumin-sensitized and – challenged mice ameliorates methacholine-induced bronchoconstriction*. (Ex. B, at Relator_000405.)

106. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent and Luminex machines. The data supposedly produced by these experiments are contained within Figures 1 (B and C), Figure 2 (B and C) and Figure 4 of the article.

107. Upon information and belief, Potts-Kant falsified the data contained within the paper.

108. This scientific paper was accepted for publication on July 18, 2011 in the American Journal of Physiology – Lung Cellular and Molecular Physiology.

109. This scientific paper, premised upon fraudulent research, cites financial support from National Heart Lung and Blood Institute Grant HL086887.

110. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *NOS2 regulation of LPS-induced airway inflammation via S-nitrosylation of NF-KB p65*

111. Potts-Kant co-authored a paper entitled *NOS2 regulation of LPS-induced airway inflammation via S-nitrosylation of NF-KB p65*. (**Ex. B, at Relator_000387.**)

112. This scientific paper, premised upon fraudulent research, cites financial support from March of Dimes (RLA) and NIH grants ES-016374 and HL-092994.

113. Upon information and belief, Potts-Kant did not actually perform the experiments at all, but rather falsified the data contained within the paper.

114. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *The Role of the Extracellular Matrix Protein Mindin in Airway Response to Environmental Airways Injury*

115. Potts-Kant co-authored a paper entitled *The Role of the Extracellular Matrix Protein Mindlin in Airway Response to Environmental Airways Injury*. (**Ex. B, at Relator_000447.**)

116. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent and Luminex machines. The data supposedly produced by these experiments are contained within Figures 1, 3, 4, and 6 of the article.

117. Upon information and belief, Potts-Kant did not actually perform the experiments at all, but rather falsified the data contained within the paper.

118. This scientific paper was accepted for publication on June 17, 2011 by the scientific journal Environmental Health Perspectives.

119. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126, ES02046, ES016347 and HL081825.

120. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *c-Kit is Essential for Alveolar Maintenance and Protection from Emphysema-like Disease in Mice*

121. Potts-Kant co-authored a scientific paper entitled *c-Kit is Essential for Alveolar Maintenance and Protection from Emphysema-like Disease in Mice*. (Ex. B, at **Relator_000105.**)

122. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 6 and 8 of the article.

123. Upon information and belief, Potts-Kant falsified the data contained within the paper.

124. This scientific paper was published in original form on July 26, 2010 by the American Journal of Respiratory and Critical Care Medicine.

125. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES015675, ES016126, ES016659, ES016347, HL077763, HL090146, HL085655 and German Ministry of Education and Research/National Genome Research Network grant NGFN2:1GR0430.

126. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *β-arrestin Deficiency Protects Against Pulmonary Fibrosis in Mice and Prevents Fibroblast Invasion of Extracellular Matrix*

127. Potts-Kant co-authored a scientific paper entitled *β-arrestin Deficiency Protects Against Pulmonary Fibrosis in Mice and Prevents Fibroblast Invasion of Extracellular Matrix*.
(Ex. B, at Relator_000076.)

128. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figure 2(B) of the article.

129. Upon information and belief, Potts-Kant falsified the data contained within the paper.

130. This scientific paper was published by the scientific journal Science Translational Medicine.

131. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants HL060539, HL077291, HL16037, HL70631 and HL016347.

132. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Particulate allergens potentiate allergic asthma in mice through sustained IgE-mediated mast cell activation*

133. Potts-Kant co-authored a scientific paper entitled *Particulate allergens potentiate allergic asthma in mice through sustained IgE-mediated mast cell activation*. (Ex. B, at Relator_000304.)

134. In contributing to this paper, Potts-Kant claimed to perform experiments on the

flexiVent machine. The data supposedly produced by these experiments are contained within Figures 1(A), Figure 2(A) and Figure 7(D) of the article.

135. Upon information and belief, Potts-Kant falsified the data contained within the paper.

136. This scientific paper was accepted for publication on December 1, 2010 by the Journal of Clinical Investigation.

137. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants AI081672, ES016347, AI056101, AI150021, AI074751, DK077307, DK077159 and DK050814.

138. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Gastrin-releasing peptide blockade as a broad-spectrum anti-inflammatory therapy for asthma*

139. Potts-Kant co-authored a scientific paper entitled *Gastrin-releasing peptide blockade as a broad-spectrum anti-inflammatory therapy for asthma*. (Ex. B, at Relator_000143.)

140. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent and Luminex machines. The data supposedly produced by these experiments are contained within Figures 1 (A and B), Figure 2 (A and B) and Figure 4 of the article.

141. Upon information and belief, Potts-Kant falsified the data contained within the paper.

142. This scientific paper was approved for publication on December 28, 2010 by the

Proceedings of the National Academy of Science.

143. This scientific paper, premised upon fraudulent research, cites financial support from Established Investigator Award from America Asthma Foundation, NIH grants AI081672 and ES016347.

144. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - Hyaluronan Fragments Contribute to the Ozone Primed Immune Response to Lipopolysaccharide

145. Potts-Kant co-authored a scientific paper entitled *Hyaluronan Fragments Contribute to the Ozone Primed Immune Response to Lipopolysaccharide*. (Ex. B, at Relator_000169.)

146. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 1 (C), Figure 2 (A and C) and Figure 4 (C) of the article.

147. Upon information and belief, Potts-Kant falsified the data contained within the paper.

148. This scientific paper was accepted for publication on September 21, 2010 by The Journal of Immunology.

149. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126, ES016659, ES016347, AI064789 and AI081672.

150. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to

apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *MARCKS-related peptide modulates in vivo the secretion of airway Muc5ac*

151. Potts-Kant co-authored a scientific paper entitled *MARCKS-related peptide modulates in vivo the secretion of airway Muc5ac*. (Ex. B, at Relator_000368.)

152. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 2 and 6 of the article.

153. Upon information and belief, Potts-Kant falsified the data contained within the paper.

154. This scientific paper was accepted for publication on June 11, 2010 by the American Journal of Physiology – Lung Cellular and Molecular Physiology.

155. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants HL82504, HL81763, HL36982, ES16347 and AI81672.

156. BioMarck Pharmaceuticals, Ltd., a pharmaceutical company located in the Research Triangle area, cites this publication in support of its COPD and asthma treatments in clinical trials.

157. Dr. Judith A. Voynow, one of the co-authors on this publication, is listed as a Scientific Advisor by BioMarck Pharmaceuticals, Ltd.

158. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Mast Cells Mediate Hyperoxia-Induced Airway Hyper-reactivity in Newborn Rats*

159. Potts-Kant co-authored a scientific paper entitled *Mast Cells Mediate Hyperoxia-Induced Airway Hyper-reactivity in Newborn Rats*. (Ex. B, at Relator_000214.)

160. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figure 2 of the article.

161. Upon information and belief, Potts-Kant falsified the data contained within the paper.

162. This scientific paper was published in July 2010 by the scientific journal Pediatric Research.

163. This scientific paper, premised upon fraudulent research, cites financial support from Children's Miracle Network, National Institutes of Child Health and Human Development grant HD043728, National Heart, Lung and Blood Institute grant HL067021 and NIH grants ES011961 and ES012496.

164. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Nitric Oxide Mediates Relative Airway Hyperresponsiveness to Lipopolysaccharide in Surfactant Protein A-Deficient Mice*

165. Potts-Kant co-authored a scientific paper entitled *Nitric Oxide Mediates Relative Airway Hyperresponsiveness to Lipopolysaccharide in Surfactant Protein A-Deficient Mice*. (Ex. B, at Relator_000269.)

166. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 1 and 7 of the article.

167. Upon information and belief, Potts-Kant falsified the data contained within the paper.

168. This scientific paper was published in original form on August 8, 2010 by the American Journal of Respiratory Cell and Molecular Biology.

169. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants 1K08-AI068822, 5P50HL084917, 5R01HL068072, 5R01HL058795, 1P30ES011961, 5R01HL084123, 5R01HL081285, 5R01HL086887-03 and HL079915.

170. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - Maternal Exposure to Particulate Matter Increases Postnatal Ozone-induced Airway Hyperreactivity in Juvenile Mice

171. Potts-Kant co-authored a scientific paper entitled *Maternal Exposure to Particulate Matter Increases Postnatal Ozone-induced Airway Hyperreactivity in Juvenile Mice*.

(Ex. B, at Relator_000233.)

172. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 2, 4 and 5 of the article.

173. Upon information and belief, Potts-Kant falsified the data contained within the paper.

174. This scientific paper was published in original form on January 21, 2009 by the American Journal of Respiratory and Critical Care Medicine.

175. This scientific paper, premised upon fraudulent research, cites financial support from Children's Environmental Health Center Award RD 83329301-0, and NIH grants ES011961 and ES016347.

176. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *NPAS3 is a tracheales homolog critical for lung development and homeostasis*

177. Potts-Kant co-authored a scientific paper entitled *NPAS3 is a tracheales homolog critical for lung development and homeostasis*. (Ex. B, at Relator_000279.)

178. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figure 4 of the article.

179. Upon information and belief, Potts-Kant did not actually perform the experiments at all, but rather falsified the data contained within the paper.

180. This scientific paper was approved for publication on May 13, 2009 by the scientific journal Proceedings of the National Academy of Science.

181. This scientific paper, premised upon fraudulent research, cites financial support from NIH grant 2R01HL44894, Established Investigator Award from the American Asthma Foundation, NIH grants ES 011961 and ES016347.

182. Publication of scientific papers premised on fraudulent research violates the terms

and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *SP-A Preserves Airway Homeostasis During Mycoplasma pneumoniae Infection in Mice*

183. Potts-Kant co-authored a scientific paper entitled *SP-A Preserves Airway Homeostasis During Mycoplasma pneumoniae Infection in Mice*. (Ex. B, at Relator_000437.)

184. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 1 and 5 (A and B) of the article.

185. Upon information and belief, Potts-Kant falsified the data contained within the paper.

186. Dr. Ledford notes in **Exhibit D**, at 5, these experiments were “bogus.”

187. This scientific paper was accepted for publication on April 20, 2009 by The Journal of Immunology.

188. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants F32HL091642, ES011961, PHL073907 and HL084917.

189. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Protection from Lipopolysaccharide-induced Lung Injury by Augmentation of Airway S-Nitrosothiols*

190. Potts-Kant co-authored a scientific paper entitled *Protection from*

Lipopolysaccharide-induced Lung Injury by Augmentation of Airway S-Nitrosothiols. (Ex. B, at Relator_000421.)

191. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 5 and 7 of the article.

192. Upon information and belief, Potts-Kant falsified the data contained within the paper.

193. This scientific paper was accepted for publication on March 25, 2009 by the American Journal of Respiratory and Critical Care Medicine.

194. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants U19-ES12469, ES11961, American Lung Association Grant RG-11485, March of Dimes, and Jean and George Brumley, Jr. Neonatal-Prenatal Research Institute.

195. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *A Robust Protocol for Regional Evaluation of Methacholine Challenge in Mouse Models of Allergic Asthma Using Hyperpolarized ³He MRI*

196. Potts-Kant co-authored a scientific paper entitled *A Robust Protocol for Regional Evaluation of Methacholine Challenge in Mouse Models of Allergic Asthma Using Hyperpolarized ³He MRI. (Ex. B, at Relator_000001.)*

197. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figure 3 (B and C) of the article.

198. Upon information and belief, Potts-Kant falsified the data contained within the paper.

199. This scientific paper was published in original form on June 2009 by the scientific journal NMR Biomed.

200. This scientific paper, premised upon fraudulent research, cites financial support from Merck & Co., Inc., NIH Grants 1P30ES0111961, 5R01HL084123, 5R01HL081285, 5R01HL086887-03, and HL079915.

201. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *NAD(P)H Quinone Oxidoreductase 1 Is Essential for Ozone-Induced Oxidative Stress in Mice and Humans*

202. Potts-Kant co-authored a scientific paper entitled *NAD(P)H Quinone Oxidoreductase 1 Is Essential for Ozone-Induced Oxidative Stress in Mice and Humans*. (Ex. B, at Relator_000249.)

203. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figure 1 of the article.

204. Upon information and belief, Potts-Kant falsified the data contained within the paper.

205. This scientific paper was published in original form on October 8, 2008 by the American Journal of Respiratory Cell and Molecular Biology.

206. This scientific paper, premised upon fraudulent research, cites financial support

from NIH grants HL082504, HL081763, ES07943, ES011961 and ES012496.

207. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *The extracellular matrix protein mindin regulates trafficking of murine eosinophils into the airspace*

208. Potts-Kant co-authored a scientific paper entitled *The extracellular matrix protein mindin regulates trafficking of murine eosinophils into the airspace*. (**Ex. B, at**

Relator_000120.)

209. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent and Luminex machines. The data supposedly produced by these experiments are contained within Figure 1 (B, C and D), Figure 2, Figure 4 (C) and Figure 8 (C and D) of the article.

210. Upon information and belief, Potts-Kant falsified the data contained within the paper.

211. This scientific paper was accepted for publication on September 3, 2008 by the Journal of Leukocyte Biology.

212. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES11961, ES12496, ES16126 and National Heart, Lung and Blood Institute grant HL91335.

213. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of

compliance made by applicants to NIH.

Publication Containing Falsified Data - *In utero supplementation with methyl donors enhances allergic airway disease in mice*

214. Potts-Kant co-authored a scientific paper entitled *In utero supplementation with methyl donors enhances allergic airway disease in mice*. (Ex. B, at Relator_000185.)

215. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 1 (A, C and D) and 4 of the article.

216. Upon information and belief, Potts-Kant falsified the data contained within the paper.

217. This scientific paper was accepted for publication on July 30, 2008 by The Journal of Clinical Investigation.

218. This scientific paper, premised upon fraudulent research, cites financial support from National Heart, Lung and Blood Institute grant HL91335.

219. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *A micro-CT analysis of murine lung recruitment in bleomycin-induced lung injury*

220. Potts-Kant co-authored a scientific paper entitled *A micro-CT analysis of murine lung recruitment in bleomycin-induced lung injury*. (Ex. B, at Relator_000319.)

221. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within

Figure 6 of the article.

222. Upon information and belief, Potts-Kant falsified the data contained within the paper.

223. This scientific paper was accepted for publication on June 13, 2008 by the Journal of Applied Physiology.

224. This scientific paper, premised upon fraudulent research, cites financial support from National Center for Research Resources, National Cancer Institute National Biomedical Technology Resource Award P41 RR-005959, U24-CA-092656 and NIH grant ES011961.

225. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Chronic LPS Inhalation Causes Emphysema-Like Changes in Mouse Lung that Are Associated with Apoptosis*

226. Potts-Kant co-authored a scientific paper entitled *Chronic LPS Inhalation Causes Emphysema-Like Changes in Mouse Lung that Are Associated with Apoptosis*. (**Ex. B, at Relator_000098.**)

227. In contributing to this scientific paper, Potts-Kant claimed to perform experiments involving the exposure of mice to certain chemicals.

228. Upon information and belief, Potts-Kant did not actually expose the mice to the chemical at all, thereby falsifying the data contained within the paper.

229. This scientific paper was published in original form on December 12, 2007 by the American Journal of Respiratory Cell and Molecular Biology.

230. This scientific paper, premised upon fraudulent research, cites financial support

from NIH grants ES11375, ES7498, ES9607, ES11961, AI58161 and HL91335.

231. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Ambient Ozone Primes Pulmonary Innate Immunity in Mice*

232. Potts-Kant co-authored a scientific paper entitled *Ambient Ozone Primes Pulmonary Innate Immunity in Mice*. (Ex. B, at Relator_000052.)

233. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figure 1 of the article.

234. Upon information and belief, Potts-Kant falsified the data contained within the paper.

235. This scientific paper was accepted for publication on July 18, 2007 by The Journal of Immunology.

236. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES12717, ES11961, National Institute of Allergy and Infectious Disease grant AI58161 and National Heart, Lung and Blood Institute grant HL91335.

237. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Hyaluronan Activation of the Nlrp3 Inflammasome*

Contributes to the Development of Airway Hyperresponsiveness

238. Potts-Kant co-authored a scientific paper entitled *Hyaluronan Activation of the Nlrp3 Inflammasome Contributes to the Development of Airway Hyperresponsiveness*. (Ex. B, at Relator_000162.)

239. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 1, 2, 3 and 5 of the article.

240. Upon information and belief, Potts-Kant falsified the data contained within the paper.

241. This scientific paper was accepted for publication on September 24, 2012 by the scientific journal Environmental Health Perspectives.

242. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126, AI081672, ES020350, ES020426, AI089756, and unrestricted educational grant from China Scholarship Counsel.

243. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - Innate Immune Activation by Inhaled Lipopolysaccharide, Independent of Oxidative Stress, Exacerbates Silica-Induced Pulmonary Fibrosis in Mice

244. Potts-Kant co-authored a scientific paper entitled *Innate Immune Activation by Inhaled Lipopolysaccharide, Independent of Oxidative Stress, Exacerbates Silica-Induced Pulmonary Fibrosis in Mice*. (Ex. B, at Relator_000193.)

245. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 5 and 9 of the article.

246. Upon information and belief, Potts-Kant falsified the data contained within the paper.

247. This scientific paper was accepted for publication on June 13, 2012 by scientific journal PLoS ONE.

248. This scientific paper, premised upon fraudulent research, cites financial support from March of Dimes, NIH grants ES016126, ES016000 and AI081672.

249. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *NAD(P)H:Quinone Oxoreductase 1 Protects Lungs From Oxidant-Induced Emphysema in Mice*

250. Potts-Kant co-authored a scientific paper entitled *NAD(P)H:Quinone Oxoreductase 1 Protects Lungs From Oxidant-Induced Emphysema in Mice*. (**Ex. B, at Relator_000242.**)

251. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent and Luminex machines. The data supposedly produced by these experiments are contained within Figures 2, 3, 4 and 5 of the article.

252. Upon information and belief, Potts-Kant falsified the data contained within the paper.

253. This scientific paper was accepted for publication on February 2, 2012 by

scientific journal Free Radical Biology & Medicine.

254. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126, ES020426 and ES16347.

255. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Hyaluron Signaling during Ozone-Induced Lung Injury Requires TLR4, MyD88, and TIRAP*

256. Potts-Kant co-authored a scientific paper entitled *Hyaluron Signaling during Ozone-Induced Lung Injury Requires TLR4, MyD88, and TIRAP*. (Ex. B, at Relator_000177.)

257. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 1, 3, 6 and 8 of the article.

258. Upon information and belief, Potts-Kant falsified the data contained within the paper.

259. This scientific paper was accepted for publication on October 11, 2011 by scientific journal Free Radical Biology & Medicine.

260. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126 and ES020426.

261. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *NADPH:Quinone Oxidoreductase 1 Regulates Host Susceptibility to Ozone via Isoprostane Generation*

262. Potts-Kant co-authored a scientific paper entitled *NADPH:Quinone Oxidoreductase 1 Regulates Host Susceptibility to Ozone via Isoprostane Generation*. (**Ex. B, at Relator_000574.**)

263. Upon information and belief, Potts-Kant falsified the data contained within the paper.

264. Upon information and belief, Potts-Kant failed to expose the mice to the ozone as the experimental protocol called for.

265. This scientific paper was published on February 15, 2013 by the Journal of Biological Chemistry.

266. This scientific paper, premised upon fraudulent research, cites financial support from NIH grant ES016836.

267. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Alveolar Macrophages from Overweight/Obese Subjects with Asthma Demonstrate a Proinflammatory Phenotype*

268. Potts-Kant co-authored a scientific paper entitled *Alveolar Macrophages from Overweight/Obese Subjects with Asthma Demonstrate a Proinflammatory Phenotype*. (**Ex. B, at Relator_000523.**)

269. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within

Table 3 of the article.

270. Upon information and belief, Potts-Kant falsified the data contained within the paper.

271. This scientific paper was accepted for publication in final form on May 27, 2012 by the American Journal of Respiratory and Critical Care Medicine.

272. This scientific paper, premised upon fraudulent research, cites financial support from American Thoracic Society grant 07-012, and NIH grants P50-HL-084917, HL-05-009, HL086887, ES016126 and AI081672.

273. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *NAD(P)H quinone oxidoreductase 1 regulates neutrophil elastase-induced mucous cell metaplasia*

274. Potts-Kant co-authored a scientific paper entitled *NAD(P)H quinone oxidoreductase 1 regulates neutrophil elastase-induced mucous cell metaplasia*. (Ex. B, at Relator_000565.)

275. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figure 3(L) of the article.

276. Upon information and belief, Potts-Kant falsified the data contained within the paper.

277. This scientific paper was published on June 1, 2012 by the American Journal of Physiology – Lung Cellular and Molecular Physiology.

278. This scientific paper, premised upon fraudulent research, cites financial support from Duke Children's Miracle Network grant, NIH grants T32HL098099, R01HL082504 and R01ES016347.

279. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - Effects of corticosteroid treatment on airway inflammation, mechanics, and hyperpolarized 3He magnetic resonance imaging in an allergic mouse model

280. Potts-Kant co-authored a scientific paper entitled Effects of corticosteroid treatment on airway inflammation, mechanics, and hyperpolarized 3He magnetic resonance imaging in an allergic mouse model.

281. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figures 6 (F) and 8 (F) of the article.

282. Upon information and belief, Potts-Kant falsified the data contained within the paper.

283. This scientific paper was accepted for publication on January 10, 2012 by the Journal of Applied Physiology.

284. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants AI081672 and NCI 1R01-CA-142842.

285. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to

apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

Publication Containing Falsified Data - *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A)^{-/-} mice*

286. Potts-Kant co-authored a scientific paper entitled Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A)^{-/-} mice.

287. In contributing to this paper, Potts-Kant claimed to perform experiments on the flexiVent machine. The data supposedly produced by these experiments are contained within Figure 3 (A, B-F), Figure 4 (C-F), and Figure 6 (A-F) of the article.

288. Upon information and belief, Potts-Kant falsified the data contained within the paper.

289. This scientific paper was accepted for publication on January 17, 2013 by the scientific Journal of Allergy and Clinical Immunology.

290. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants F32-HL091642 and PO1-AI81672.

291. Publication of scientific papers premised on fraudulent research violates the terms and conditions of the NIH grants awarded to fund the research. The use of this scientific paper to apply for and obtain additional NIH grants constitutes a violation of the certificates of compliance made by applicants to NIH.

DUKE UNIVERSITY'S RECKLESS SUPERVISION

292. The only other flexiVent machine in the Pulmonary Division was within the laboratory of Dr. Julia Walker. Barbara Theriot operated the flexiVent in Dr. Walker's laboratory and was Potts-Kant's peer in terms of both job title and experience.

293. Dr. Foster would become defensive and refuse to collaborate with anyone who

was also collaborating with Dr. Walker's Laboratory or Barbara Theriot.

294. Potts-Kant took a relatively short period of time, approximately three minutes, to process mice through the flexiVent machine. In contrast, Barbara Theriot with the Walker Laboratory took approximately 20 minutes per mouse. Both Potts-Kant and Barbara Theriot were equally experienced on the flexiVent machine.

295. In the six years in which Potts-Kant worked in the Pulmonary Division, at no time did anyone review her data for accuracy, nor did anyone compare the data Potts-Kant reported with the raw data produced and stored by the machines.

296. Potts-Kant was a Duke Purchase-Card ("P-Card") holder. A P-Card is a Duke University-issued credit card that is linked to grant funds. Their use is supposed to be tightly controlled.

297. In 2011, Potts-Kant used a Duke University P-Card to purchase all the alcohol and meals when a group of Pulmonary Division personnel went out to dinner. Dr. Ledford noticed that Potts-Kant used her Duke University P-Card to pay the bill and asked her how that was an allowable use of the P-Card. Potts-Kant responded to the effect, "No one looks at the invoices."

298. Dr. Ledford reported this incident to Julia Peterson in the Business Office of the Pulmonary Division. Upon information and belief, no action was taken.

299. Under the circumstances, Dr. Foster knew or should have known that the data reported by Potts-Kant was manipulated or fraudulent.

300. Dr. Foster's supervision of Potts-Kant was reckless.

301. Dr. Ledford informed Relator Thomas that for some experiments supposedly conducted by Potts-Kant, no raw data exists at all, indicating that these experiments did not take

place.

302. Relator Thomas has seen additional documents similar to those in Exhibit A that demonstrate the discrepancies between actual raw data and the fraudulent data produced by Potts-Kant and used by Duke University. Because he does not have access to these documents, he is able to only provide a representative sample.

303. Relator Thomas has discussed this research fraud with Dr. Ledford, Dr. Que and other Pulmonary Division personnel. Based upon their statements to him, he understands that at this point, all work completed by Potts-Kant is likely manipulated or fraudulent in some manner.

DISCOVERY OF RESEARCH FRAUD BY DUKE UNIVERSITY

304. In addition to committing widespread research fraud, Potts-Kant embezzled grant funding in order to make personal online purchases over a four year period between 2008 and 2012. To complete this embezzlement, she produced false invoices for scientific equipment and supplies for reimbursement. Upon information and belief, the total amount embezzled by Potts-Kant exceeded \$14,000.

305. Between November 2012 and March 2013, the Business Office of the Pulmonary Division of Duke University Medical Center discovered the embezzlement of grant funds by Potts-Kant. Julia Peterson, the Business Manager, discovered the embezzlement during a routine cost-savings analysis. In an effort to find savings, the Business Office attempted to locate cheaper laboratory supplies and equipment than those “purchased” by Potts-Kant. In doing so, the Business Office discovered that many of the laboratory equipment and supply purchases were fraudulent.

306. Julia Peterson placed Potts-Kant on leave in the first week of March 2013. Durham Police Department charged Potts-Kant with Felony Embezzlement on March 31, 2013.

307. In the aftermath of the embezzlement discovery, the researchers within the Pulmonary Division found that raw data produced by Potts-Kant in the course of running experiments differed from the results she reported.

308. From approximately March 15, 2013 to present, the personnel with whom Potts-Kant conducted research have begun analyzing their data to confirm its reliability. In all cases, the researchers are finding that their data is either manipulated or fraudulent.

309. On April 23, 2013, a department meeting was held within the Pulmonary Division. Dr. Kraft informed the assembled researchers that widespread research fraud was suspected on experiments Potts-Kant worked on, and that individual researchers were to attempt to run new experiments in the hopes of getting the same results.

310. Dr. Kraft told Dr. Ledford that if researchers were able to get the same results as those reported in the publications, no further action would be taken. If the results cannot be replicated, indicating the data was fraudulent, the researchers were to notify journals and publications to print small, limited retractions.

311. At no time did Dr. Kraft indicate that Duke University intended to report this information to the grant agencies involved or share this information in a transparent manner. To the contrary, Dr. Kraft stated that all communications regarding this research fraud would be conducted in person, in order to “avoid creating a paper trail.”

312. Relator Thomas has seen a “script” circulating within the Pulmonary Division with instructions on how to communicate the research fraud situation to co-authors of papers. The script states that Potts-Kant was involved in an employment situation and that Duke University is currently reviewing the situation. The script does not provide the co-authors with accurate information regarding the research fraud.

313. Defendant Duke University has knowingly made false statements and representations to the United States Government by virtue of (1) providing false reports and summaries of research results; (2) by providing the names of fraudulent scientific papers in support of its grant funding; (3) by falsely certifying compliance with 42 C.F.R Parts 50 and 93, the NIH Grants Policy Statement, and all Federal laws and regulations; and (5) by fraudulently and wrongfully withholding grant funds after discovering the fraud and lack of compliance with the grant terms and conditions.

314. By virtue of the above, it is clear that Defendant Duke University knowingly made false statements to the United States Government that are in violation of the False Claims Act.

315. Further auditing and analysis will uncover more products and more false statements.

COUNTS

COUNT ONE

Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)¹ (Potts-Kant and Duke University Health System, Inc.)

316. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

317. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C § 3729(a)(1)(A).

318. At all relevant times, Potts–Kant was acting within the scope of her employment

¹ To the extent wrongdoing occurred prior to May 20, 2009, this Amended Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730 (a)(1).

by Duke University Health System, Inc., and for the benefit of Duke University Health System, Inc.

319. Potts-Kant knowingly² submitted requests for payment of grant funds for research based on manipulated data.

320. Potts-Kant knowingly procured and used federal research grant funding to conduct experiments, and to continue experiments, on which she manipulated and/or altered the experiment results.

321. Potts-Kant knowingly submitted grant applications using manipulated data to form the basis of the request for grant monies.

322. Potts-Kant submitted or caused the submission of claims³ in the form of grant applications, grant interim progress reports, and grant closeout reports based on falsified and manipulated data.

323. Potts-Kant was a managerial employee in her position of clinical coordinator. In addition, Dr. Foster acted as Potts-Kant's supervisor, and he had knowledge of her actions, ratified them, or was reckless in his supervision of her.

324. Duke University Health System, Inc., through Dr. Foster, was reckless in its supervision of Potts-Kant.

325. The Defendants Potts-Kant and her employer, Duke University Health System, Inc., knowingly submitted or caused the submission of false claims in violation of 31 U.S.C. § 3729.

326. The United States, unaware of the falsity or fraudulent nature of the claims caused

² As the term "knowingly" is defined by 31 U.S.C. § 3729(b)(1). To the extent the term "knowingly" is used in this Count, it is uniformly used as the term is defined in 31 U.S.C. § 3729(b)(1).

³ As the term "claim" is defined by 31 U.S.C. § 3729(b)(2). To the extent the term "claim" is used in this Count, it is uniformly used as the term is defined in 31 U.S.C. § 3729(b)(2).

by Defendants Potts-Kant and her employer, Duke University Health System, Inc., paid for claims that otherwise would not have been allowed.

327. Defendants Potts-Kant and her employer, Duke University Health System, Inc., violated 31 U.S.C. § 3729 and have thereby damaged and continue to damage the United States Government by their actions in a substantial amount.

COUNT TWO
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)⁴
(Dr. William M. Foster and Duke University Health System, Inc.)

328. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

329. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C § 3729(a)(1)(A).

330. At all relevant times, Dr. Foster was acting within the scope of his employment by Duke University Health System, Inc., and for the benefit of Duke University Health System, Inc.

331. Dr. Foster knowingly⁵ submitted requests for payment of grant funds for research based on manipulated data.

332. Dr. Foster knowingly procured and used federal research grant funding to conduct experiments, and to continue experiments, on which Potts-Kant manipulated and/or altered the experiment results.

333. Dr. Foster knowingly submitted grant applications using manipulated data to form the basis of the request for grant monies.

⁴ To the extent wrongdoing occurred prior to May 20, 2009, this Amended Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730 (a)(1).

⁵ As the term “knowingly” is defined by 31 U.S.C. § 3729(b)(1). To the extent the term “knowingly” is used in this Count, it is uniformly used as the term is defined in 31 U.S.C. § 3729(b)(1).

334. Dr. Foster knowingly submitted or caused the submission of claims⁶ in the form of grant applications, grant interim progress reports, and grant closeout reports based on falsified and manipulated data.

335. Dr. Foster was a managerial employee in his position of Principal Investigator for Duke University Health System, Inc., and he managed Potts-Kant.

336. The Defendants Dr. Foster and his employer, Duke University Health System, Inc., knowingly submitted or caused the submission of false claims in violation of 31 U.S.C. § 3729.

337. The United States, unaware of the falsity or fraudulent nature of the claims caused by Defendant Foster and his employer, Duke University Health System, Inc., paid for claims that otherwise would not have been allowed.

338. Defendant Foster and his employer, Duke University Health System, Inc., violated 31 U.S.C. § 3729 and have thereby damaged and continue to damage the United States Government by their actions in a substantial amount.

COUNT THREE
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B)⁷
(Potts-Kant and Duke University Health System, Inc.)

339. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

340. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C § 3729(a)(1)(B).

⁶ As the term “claim” is defined by 31 U.S.C. § 3729(b)(2). To the extent the term “claim” is used in this Count, it is uniformly used as the term is defined in 31 U.S.C. § 3729(b)(2).

⁷ To the extent wrongdoing occurred prior to May 20, 2009, this Amended Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730 (a)(1).

341. At all relevant times, Erin Potts-Kant was acting within the scope of her employment by Duke University Health System, Inc., and for the benefit of Duke University Health System, Inc.

342. Potts-Kant knowingly⁸ made or caused to be made a false certification certifying compliance with the N.I.H. Grants Policy Statement and 42 CFR parts 50 and 93.

343. These false certifications were prepared for each grant application, grant interim progress report, and grant closeout report.

344. Upon information and belief, these false certifications were signed by Potts-Kant on her behalf and on behalf of Dr. William Foster.

345. The aforementioned certifications were false and at the time the certifications were made Potts-Kant knew that the laboratory and the experiments in question were not in compliance with federal regulations or NIH policy requirements.

346. The certification of compliance with the regulations and NIH policy requirements were material to the Government's decision to approve the release of grant funding to Duke University Health System, Inc.

347. Potts-Kant was a managerial employee in her position of clinical coordinator. In addition, Dr. William M. Foster acted as Potts-Kant's supervisor, and he had knowledge of her actions, ratified them, or was reckless in his supervision of her.

348. Duke University Health System, Inc., through Dr. William M. Foster, was reckless in its supervision of Potts-Kant.

349. The Defendants Potts-Kant and her employer, Duke University Health System,

⁸ As the term "knowingly" is defined by 31 U.S.C. § 3729(b)(1). To the extent the term "knowingly" is used in this Count, it is uniformly used as the term is defined in 31 U.S.C. § 3729(b)(1).

Inc., knowingly made or caused to be made a false record or statement material to a false claim⁹.

350. The United States, unaware of the falsity or fraudulent nature of the certifications made or caused to be made by Defendants Potts-Kant and her employer, Duke University Health System, Inc., paid for claims that otherwise would not have been allowed.

351. Defendants Potts-Kant and her employer, Duke University Health System, Inc., violated 31 U.S.C. § 3729 and have thereby damaged and continue to damage the United States Government by their actions in a substantial amount.

COUNT FOUR
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B)¹⁰
(Dr. William M. Foster and Duke University Health System, Inc.)

352. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

353. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

354. At all relevant times, Dr. William M. Foster was acting within the scope of his employment by Duke University Health System, Inc., and for the benefit of Duke University Health System, Inc.

355. Dr. William M. Foster knowingly¹¹ made or caused to be made a false certification certifying compliance with the N.I.H. Grants Policy Statement and 42 CFR parts 50

⁹ As the term “claim” is defined by 31 U.S.C. § 3729(b)(2). To the extent the term “claim” is used in this Count, it is uniformly used as the term is defined in 31 U.S.C. § 3729(b)(2).

¹⁰ To the extent wrongdoing occurred prior to May 20, 2009, this Amended Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730 (a)(1).

¹¹ As the term “knowingly” is defined by 31 U.S.C. § 3729(b)(1). To the extent the term “knowingly” is used in this Count, it is uniformly used as the term is defined in 31 U.S.C. § 3729(b)(1).

and 93.

356. These false certifications were prepared for each grant application, grant interim progress report, and grant closeout report.

357. Upon information and belief, these false certifications were signed by Dr. William M. Foster or by Potts-Kant on behalf of Dr. William Foster.

358. The aforementioned certifications were false and at the time the certifications were made Dr. William M. Foster knew, or in reckless disregard of the truth or falsity of the information, that the laboratory and the experiments in question were not in compliance with federal regulations or NIH policy requirements.

359. The certification of compliance with the regulations and NIH policy requirements were material to the Government's decision to approve the release of grant funding to Duke University Health System, Inc.

360. Dr. William M. Foster was a managerial employee in his position of Principal Investigator for Duke University Health System, Inc., and he managed Potts-Kant.

361. The Defendants Dr. William M. Foster and his employer, Duke University Health System, Inc., knowingly made or caused to be made a false record or statement material to a false claim¹².

362. The United States, unaware of the falsity or fraudulent nature of the certifications made or caused to be made by Defendants Dr. William M. Foster and his employer, Duke University Health System, Inc., paid for claims that otherwise would not have been allowed.

363. Defendants Dr. William M. Foster and his employer, Duke University Health System, Inc., violated 31 U.S.C. § 3729 and have thereby damaged and continue to damage the

¹² As the term "claim" is defined by 31 U.S.C. § 3729(b)(2). To the extent the term "claim" is used in this Count, it is uniformly used as the term is defined in 31 U.S.C. § 3729(b)(2).

United States Government by their actions in a substantial amount.

COUNT FIVE
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(G)¹³
(Duke University and Duke University Health System, Inc.)

364. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

365. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C § 3729(a)(1)(G).

366. In March 2013, Duke University Health System, Inc., and Duke University, through its Office of Research Support, learned of the facts pled herein and of the existence of falsified and manipulated information in research papers, grant applications, and they learned of the false claims and false certifications pled herein.

367. Duke University Health System, Inc., and Duke University, through its Office of Research Support, knowingly¹⁴ concealed the aforementioned information and knowingly and improperly avoided advising the Government of the facts pled herein.

368. Instead, the defendants embarked on a coordinated strategy to conceal the information pled herein.

369. The United States, therefore, has not been properly reimbursed for the funds procured through impermissible means under the False Claims Act.

370. Defendants Duke University and Duke University Health System, Inc., violated 31 U.S.C. § 3729 and have thereby damaged in continued to damage the United States

¹³ To the extent wrongdoing occurred prior to May 20, 2009, this Amended Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730 (a)(1).

¹⁴ As the term “knowingly” is defined by 31 U.S.C. § 3729(b)(1). To the extent the term “knowingly” is used in this Count, it is uniformly used as the term is defined in 31 U.S.C. § 3729(b)(1).

Government by their actions in a substantial amount.

COUNT SIX
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)
(Duke University and Duke University Health System, Inc.)

371. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

372. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C § 3729(a)(1)(G).

373. In March 2013, Duke University Health System, Inc., and Duke University, through its Office of Research Support, learned of the facts pled herein and of the existence of falsified and manipulated information in research papers, grant applications, and they learned of the false claims and false certifications pled herein.

374. Since the time Duke University and Duke University Health Systems, Inc., discovered the widespread research fraud and embezzlement within the Pulmonary Division, they have continued to re-submit applications for grants, interim progress reports for grants, and close-out reports for grants. In these applications and reports, Defendants Duke University and Duke University Health Systems, Inc., made certifications of compliance with all applicable grant policies and regulations.

375. These false certifications were prepared for each grant application, grant interim progress report, and grant closeout report.

376. The aforementioned certifications were false and at the time the certifications were made Duke University and Duke University Health Systems, Inc., knew that the laboratory and the experiments in question were not in compliance with federal regulations or NIH policy requirements.

377. The certification of compliance with the regulations and NIH policy requirements were material to the Government's decision to approve the release of grant funding to Duke University Health System, Inc. and Duke University.

378. Defendants Duke University and Duke University Health System, Inc., violated 31 U.S.C. § 3729 and have thereby damaged in continued to damage the United States Government by their actions in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relator Thomas prays for judgment against Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. §3729 *et. seq.*
2. That this Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendant's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of 31 U.S.C. §3729 *et. seq.* or any other applicable regulations;
3. That the Relator be awarded all reasonable attorneys' fees and costs, pursuant to 31 U.S.C. Section 3730 (d)(1) and subsection (d)(2);
4. That in the event the United States Government continues to proceed with this action, the Relator be awarded an amount for bringing this action of at least 15% but not more than 25% of the proceeds of any award or the settlement of the claims;
5. That in the event the United States Government does not proceed with this action, the Relator be awarded an amount that the Court decides is reasonable for collecting the civil penalty and damages, which shall be not less than 25% nor more than 30% of the proceeds of any award or settlement;
6. That the Relator be awarded the maximum amount allowed pursuant to §3729(d) of the

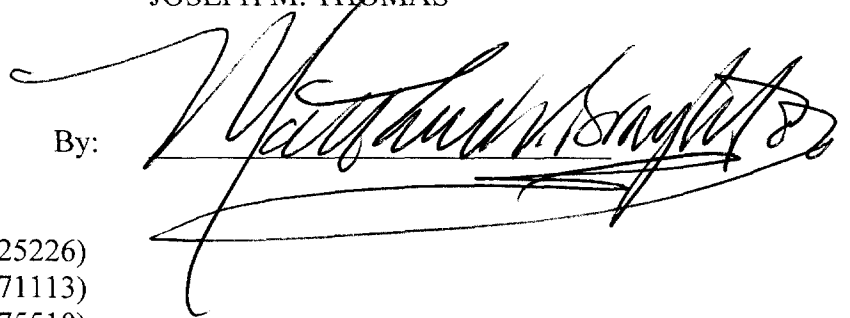
False Claims Act;

7. That the Relator be awarded pre-judgment and post judgment interest;
8. That a trial by jury be held on all issues;
9. That the Relator be awarded all costs and expenses of this action; and
10. That the United States Government and the Relator receive all other further relief that the Court deems just and proper.

Respectfully submitted,

JOSEPH M. THOMAS

By:

A handwritten signature in black ink, appearing to read "Matthew Broughton", is written over a horizontal line. The signature is stylized with a large, sweeping initial 'M' and a trailing flourish.

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